

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of August 2, 2007 in which claims 47-59 are pending and were rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections - 35 USC § 102

Claims 47, 48, 50, 52, 53 and 59 were rejected under 35 U.S.C. §102(b) as being anticipated by Klumpp, U.S. Patent No. 2,724,736. Applicants respectfully traverse this rejection because Klumpp does not teach or describe each and every element of the claimed invention.

For example, Klumpp does not teach “a *monolithic* catheter hub...wherein the proximal hub portion and the distal strain relief portion are monolithically molded as a single piece of a single material. The bushing of Klumpp is made from at least three separate pieces: body portion 1, key member 11 and mounting plate 5. See, for example, figure 3. If the proximal portion of the bushing comprises separate and separatable pieces, it can hardly be said that proximal portion of the bushing is monolithically molded with the distal portion as a single piece of material. For this reason, the bushing of Klumpp is not monolithic as required by the claim language.

Moreover, the strain-relief bushing of Klumpp is not, and would not be understood to be a catheter hub by those of skill in the art. In the Response to Arguments on page 4 of the Office Action, the Examiner argues “that even though Klumpp calls his device a ‘bushing’ it does still read on the limitations of the claims and furthermore, there is no part of the claims that specifies the device is for medical use.” As to the first part, whether Klumpp reads on the claim limitations, see the discussion above with regard to whether the device of Klumpp is monolithic. As to the assertion that there is no part of the claims that specifies the device is for medical use, this is incorrect. The terms “catheter” and “catheter hub” are used, so far as the applicants are aware, exclusively in the medical arts. See for example www.answers.com/catheter. And it is understood with even more force that a catheter hub is used with a catheter. Applicants are unaware of any catheter hubs that are not contemplated to be used with a catheter. Therefore, whether Klumpp can be used in the medical arts and as a catheter hub is of particular

relevance to whether Klumpp anticipates any of the claims. As explained previously, the bushing of Klumpp is not a catheter hub; it is not at the proximal end of the conduit and does not appear to be able to connect other catheters, syringes or therapeutic devices fluidly to the lumen of a catheter. Further, while the crimping-style lock of Klumpp may be suitable for use with an electrical conduit, which is solid, there is nothing to suggest that such a lock could fix a flexible, hollow catheter in place. Therefore, it cannot be said that Klumpp discloses a catheter hub.

Therefore, for at least the reasons that the bushing of Klumpp is not monolithic and is not a catheter hub, applicants respectfully submit that claim 47 is not anticipated by Klumpp. As claims 48, 50, 52, 53 and 59 depend from claim 47 and contain additional elements, applicants submit that these claims are in condition for allowance as well.

Claim Rejections - 35 USC § 103

Claims 47-50, 52-54 and 56-59 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldenberg et al., U.S. Patent No. 5,352,198 as modified by Davila, U.S. Patent No. 5,466,230. Applicants respectfully traverse the rejection because the cited references do not teach or suggest all the claim elements.

For example, claim 47 recites “wherein the proximal hub portion and the distal strain relief portion are monolithically molded as a single piece of a single material.” The examiner argues, briefly that Goldenberg et al. disclose a monolithic hub and that Davila provides the motivation for modifying this monolithic hub with transverse grooves to protect the catheter from bending or kinking. The problem with the examiner’s position is that neither reference disclose such a strain relief portion monolithically molded with a proximal hub portion.

The examiner takes Figure 1 of Goldenberg et al. to show that hub portion 32 and strain relief 28 are monolithically molded together. Applicants agree with the Examiner to the following extent: If—and only if—Goldenberg were silent as to the proximal hub, Figure 1 might well support the assertion that the hub and strain relief are one piece. However, Goldenberg is not silent on this feature. Goldenberg describes the hub in sufficient detail that readers know that the hub of Goldenberg is not monolithic.

The Examiners position that the hub and strain relief of Goldenberg are monolithic appears to be based on an erroneous understanding of drafting conventions. When portions of an assembly are drawn distinctly—separated by lines or having different cross-hatching, for example, it is understood those distinct portions of the drawings are distinct portions of the assembly such as separate components or separate subassemblies. This is a drafting convention. However, the Examiner appears to be under the impression that a portion that shares an outline and a cross-hatching scheme is a monolithic portion of the device. This is erroneous. Such a portion may well depict a subassembly whose details are not necessary in the current figure. This is the drafting convention. Another drafting convention is that drawings are interpreted in light of the title block, key and other text.

Here, the figures of Goldenberg, interpreted in light of the specification contradict the Examiner's position that Figure 1 depicts a stress relief monolithically molded with the catheter hub:

Returning to FIG. 1, an optional stress relief sleeve 28 is mounted about the rear portion 30 of proximal end 12 to facilitate handling of the catheter. Additionally, a hub 32 is attached to the stress relief sleeve (or directly to the catheter if no stress relief sleeve is present) to facilitate attachment of the catheter to appropriate drainage devices (not shown).

Column 3, lines 3-9. Goldenberg teaches that the strain relief and the hub are two separate pieces, attached together during manufacturing. That the hub and strain relief are shown as having a common outline and cross-hatching in Figure 1 does not tell us anything about whether the hub and strain relief are monolithic as in claim 47; it merely suggests the relative unimportance of these proximal components to the invention of Goldenberg et al.

If the Examiner persists in maintaining that Goldenberg discloses a monolithically molded hub assembly, an explanation of why the Examiner interprets Figure 1 in a manner contrary to the specification of Goldenberg would be of great benefit. Such an explanation will help in clarifying the issues and sharpening the arguments for appeal. It must be remembered that drawings can be used only “on the basis of what they reasonably disclose and suggest to one skilled in the art.” *In re Baum*, 153 U.S.P.Q. 190, 195 (1967). While it does not matter whether a feature shown in a drawing was unintended or unexplained in the specification, it is of vital importance whether a feature

was in fact disclosed. And as applicants have explained above, no monolithic strain relief and hub was disclosed by the drawings.

Likewise, in Davila, spring 15 and hub 14 are not monolithically formed but rather the spring 15 is embedded in the hub 14 during the process of forming the hub. See Figure 3 and column 3, lines 46-59 of Davila, for example.

Applicants therefore respectfully submit that neither Goldenberg et al. nor Davila disclose, singly or in combination, each and every element of claim 47. As claims 48-50 and 52-53 depend therefrom and contain additional elements, applicants submit that these claims are in condition for allowance as well.

As independent claim 54 recites “wherein the monolithic hub is monolithically molded as a single piece of a single material,” applicants submit that this claim is in condition for allowance for at least the reasons given up with respect to claim 47. As claims 56-59 depend therefrom and contain additional elements, applicants submit that these claims are in condition for allowance as well.

Claim 51 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldenberg et al. as modified by Davila in further view of Wijkamp et al, U.S. Patent No. 5,167,647 and claim 55 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldenberg as modified by Davila in further view of Bartholomew, U.S. Patent No. 4,802,947. Applicants respectfully traverse the rejections.

For at least the reason that claims 51 and 55 depend from claim 47 and 54, respectively, which applicants submit are allowable, and contain additional elements, applicants submit that these claims are in condition for allowance as well.

Claims 54, 56, 57 and 58 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Klumpp as modified by Goldenberg et al. Applicants respectfully traverse the rejection.

As a preliminary matter, applicants respectfully disagree that Klumpp is analogous (and thus proper) prior art. “In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem

with which the inventor was concerned.” *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). A bushing is a circular fitting which is put on a conduit to provide protection to the conduit. A catheter hub is a device affixed to the proximal end of a catheter to make it easy to grasp the catheter, thread other devices through the catheter lumen and connect the catheter to other devices. A bushing is therefore not reasonable pertinent to a catheter hub and would not commend itself to the attention of one developing improved hubs in the catheter art area.

The examiner argues briefly, that one would insert a catheter as taught by Goldenburg et al. into the bushing of Klumpp because such a modification would allow the device of Klumpp to provide support and prevent kinking and bending of a tube to be used in a medical application. However, claim 54 recites “a monolithic hub.” As discussed above with respect to claim 47, the bushing of Klumpp is neither monolithic nor a hub; it is not molded as a single piece of a single material and one of skill in the art would not understand the bushing of Klumpp to be a hub.

Goldenberg et al. already discloses providing a strain relief support 28. As to the supposed advantages of having alternatives, such alternatives can only be a possibility if they are not inferior to the existing device. In this case, the bushing of Klumpp is so ill-suited to the purpose of a catheter hub as to not be a viable alternative hub for medical use. The bushing of Klumpp uses a crimping-type locking mechanism to attach the bushing to a conduit. Crimping would distort the inner lumen, making it difficult or impossible to insert and remove stiffening cannula 60, for example. And while crimping appears to be a way to secure the bushing onto a solid conduit, there is little chance that crimping would secure the bushing in place on a thin-walled flexible catheter. Further, the bushing of Klumpp is apparently designed to be attached on an intermediate portion of a conduit and not at an extremity, which further renders the bushing unsuitable for use as a catheter hub. In any case, neither the proximal end of a catheter nor the proximal end of the bushing is configured to be attached to a drainage device, which makes the proposed catheter device unsuitable for the purpose described in Goldenberg et al. of attaching the catheter to an appropriate drainage device and draining fluid from the catheter. All of these reasons lead to the conclusion that there is no prima facie case of obviousness; there is motivation to make the proposed modification; the modified

medical device would undoubtedly be inferior to that described by Goldenberg et al. and there is no reasonable likelihood that such a device would work.

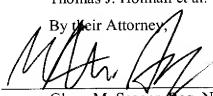
For at least these reasons, applicants respectfully submit that no prima facie case of obviousness has been made and that claim 54 is in condition for allowance. As claims 56, 57 and 58 depend therefrom and contain additional elements, applicants submit that these claims are in condition for allowance as well.

In view of the foregoing, all pending claims, namely claims 47-59, are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,



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